

engages with said ultrasound source or detector housing or frame, wherein the holder configured to be compatible with a plurality of differently sized ultrasonic probes.

Please add the following claims:

82 ~~79~~. The device of claim 1, wherein , the securing portion of the holder configured to secure a plurality of differently sized ultrasonic probes.

83 ~~80~~. The hygienic removable holder of claim 30 further including a collar which secures the probe within the holder, said collar being configured to received more than one size probe.

Remarks

In the non-final Office Action mailed February 26, 2002, the Examiner indicated that claims 1-35, 60-62 and 70-78 are pending in the application, of which claims 20-29 are withdrawn from consideration. Claims 1-19, 30-35, 60-62 and 70-78 have been rejected. Claims 1, 19, 30, 60, 61, 70, 71 and 75 are amended by this amendment. Claims 79 and 80 have been added. Reconsideration and allowance of the claims as amended is respectfully requested.

Claims 1, 12-16, 30-32 have been rejected as anticipated by U.S. Patent No. 4,796,632, listing Boyd et al. as the inventors (the "Boyd" patent). The Examiner contends that the Boyd patent teaches "a holder for securing portion members and rigid housing e.g. 12 than and having acoustically transmissive window 18, and wherein the widow is size-matched to the retained ultrasound probe." [See Office Action, February 26, 2002, p. 2.] While not acceding to the correctness of the examiner's rejection, claims 1 and 30 have been amended to further advance prosecution of the present application. Claim 1, as amended, recites that the distance between the interrogation surface of the probe and the interrogation window is less than approximately 1 cm. Support for the claim amendment can be found illustrated in Figures 2B and 2C and the text

describing the illustrations. Claim 30 has been amended in a similar manner. None of the references cited by the examiner, including the Boyd patent, provide a teaching for such a configuration. The Boyd patent discloses a “standoff” adapter. As described by Boyd, to provide better field imaging a standoff adapter can be used to keep the probe separated and away from the interrogation surface. These standoff adapters can increase the distance between the probe and the interrogation surface between 1 cm and 4 cm. Increased distance is desirable to improve near field imaging. Since the Boyd patent describes a “standoff” adapter, the reference clearly does not anticipate the claims since they now recite the close proximity between the interrogation window and the probe when the holder is on the probe. Additionally, claims 1 and 30 have been amended to recite the hygienic features of the present invention. The claims, as amended, are not anticipated or fairly suggested by the art cited by the examiner. Accordingly, the above referenced claims are allowable over the art cited by the examiner.

Claims 2-5, 9-12, 33, 60-62, 70, 75-78 are rejected as being unpatentable over the Boyd patent in view of U.S. Patent No. 5,897,503 listing Lyon et al. as inventors (the “Lyon” patent). The examiner contends that it would have been obvious “in view of the latter [Lyon patent] to manufacture probe holder portions out of injection molded plastic polymers.” [See Office Action dated February 26, 2002, p. 3.] Claims 2-5, 9-12 and 33 depend from claims discussed above and, accordingly, are patentable at least because of their dependence from the claims discussed above, and the novel and unobvious features recited in the claims.

Without acceding the correctness of the examiner’s position regarding claim 60, the claim has been amended to recite that the holder includes a predetermined amount of acoustic gel. Neither the Boyd patent nor the Lyon patent disclose such a feature. The predetermined amount of acoustic gel included with the holder facilitates the handling of the holder with the

probe and allows an operator to begin an acoustic procedure more quickly. Moreover, since a predetermined amount of gel is provided, there is a reduced likelihood of wasting the gel. Accordingly, claim 60 is allowable over the prior art of record. Claims 61 and 62 are allowable at least because they depend from claim 60 and the novel and unobvious features recited in the claims.

Claims 70 and 75 have been amended to recite that the probe is configured to receive differently sized probes. Since none of the prior art cited by the examiner provides such a teaching, claims 70 and 75 are allowable over the prior art of record. Claims 76-78 are allowable because they depend from claim 75 and the novel and unobvious features recited therein.

Claims 6-8, 17-18, 34-35, are rejected as being obvious because of the Boyd patent. These claims are allowable because they depend from a claim discussed above and the novel and unobvious features recited therein.

Claim 19 has been rejected as being unpatentable over the Boyd patent in view of U.S. Patent No. 4,688,578, listing Takano et al. as inventors (the "Takano" patent). According to the examiner Tanako discloses stackable sets of holders since there are no internal protrusions. It is unclear what the examiner is considering a stacking portion in Tanako. Claim 19 recites a plurality of holders which are stackable. This is clearly not shown in Tanako. The stackable feature is advantageous for several reasons. The shipping and storage of the holders is more efficient and takes up less space. Additionally, the stacking feature of the holder makes it easier to use because it reduces the fumbling that may occur if the holders are not stacked together. Accordingly, claim 19 is allowable over the prior art of record.

Claims 71-74 are rejected as being unpatentable over the Boyd patent "alone or further in view of [the Lyon patent] as applied to claims above, and further in view of [U.S. Patent No. 4,383,533 issued to] Bhagat et al." [See Office Action dated February 26, 2002, p. 4.] The examiner considers the Bhagat patent to teach the "close association" of the use of the recited drugs with ultrasound monitoring. The claim recites a kit which includes a holder and the recited drugs. None of the references cited provide the teaching for or suggesting of the kit recited in the claims. Accordingly, claims 71-74 are allowable over the prior art cited by the examiner.

Claims 79 and 80 have been added by this amended by this response. The newly added claims recite the feature that the holder is adaptable to receive differently sized probes. In claim 79, the securing portion of the holder is configured to secure a plurality of differently sized ultrasonic probes. Claim 80 recites a collar which secures the probe within the holder, collar is recited as being configured to receive more than one size probe.

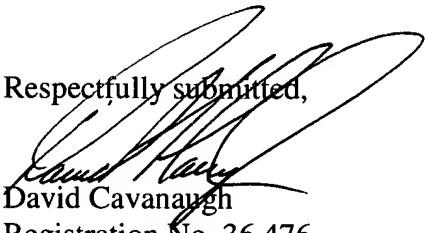
In view of the amendments and arguments made above, Applicants conclude that the outstanding rejections of record have been overcome. The present invention is, thus, now believed to be in condition for allowance. A timely Notice of Allowance is respectfully requested.

If there are any payments due or credits owed, please make them to our Deposit Account No. 08-0219.

The Examiner is encouraged to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

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Attachment: Clean version of claims as amended

Clean Version of Claims as Amended
USSN 09/314,206
Filed May 9, 1999
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- B¹
1. A device for hygienic ultrasonic interrogation of a skin interrogation site, comprising:
- c) a holder for an ultrasonic probe adapted for hygienic skin-interrogation of tissues subjacent to a skin interrogation site, said holder is adapted to fit at least an interrogation surface of said ultrasonic probe, and said holder includes 1) a securing portion for securing said holder to said ultrasonic probe and 2) an interrogation window in acoustic alignment with at least a section of said interrogation surface, and
 - d) a sonolucent film covering said interrogation window, wherein the distance between the interrogation surface of the probe and the interrogation window is less than approximately 1 cm.

- B²
19. A device for ultrasonic interrogation from a skin interrogation site, comprising:
- a plurality of holders for an ultrasonic probe adapted for skin-interrogation of tissues subjacent to a skin interrogation site, said holder is adapted to fit at least an interrogation surface of said ultrasonic probe, and said holder includes 1) a securing portion for securing said holder to said ultrasonic probe and 2) an interrogation window in acoustic alignment with at least a section of said interrogation surface, and a sonolucent film covering said interrogation window, wherein each holder has an exterior contour and an interior contour and said exterior contour is configured to fit into an interior contour of another holder.

B³ 30. A hygienic removable holder for an ultrasound probe, said removable holder comprising a proximal region for interrogation of an exterior interrogation surface, said proximal region is adapted for acoustic alignment with an ultrasound source or detector, said proximal region includes an interrogation surface that permits interrogation with an ultrasound probe and a distal region slidably engagable with said ultrasound probe while maintaining said acoustic alignment, wherein the distance between the interrogation surface of the probe and the interrogation window is less than approximately 1 cm so the probe is close to but not directly touching the interrogation surface during an ultrasound interrogation.

B⁴ 60. An injection molded device, comprising a rigid, plastic holder for an ultrasound source or detector, said rigid, plastic holder is of a generally predetermined shape and three dimensional dimensions without an inserted ultrasound source or detector, said rigid, plastic holder comprising an interrogation region for interrogation of an exterior interrogation surface, said interrogation region is dimensioned to snugly fit over a housing for said ultrasound source or detector while permitting interrogation through said interrogation region and said interrogation region engages with said housing, wherein the holder includes a predetermined quantity of acoustic gel material.

61. The injection molded device of claim 60, wherein the predetermined quantity of acoustic gel material comprises a machine applied acoustic gel layer on said interrogation region to facilitate acoustic coupling between said interrogation region and said ultrasound source or detector.

B⁵ 70. An ultrasound system, comprising:

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- d) a rigid, plastic holder for an ultrasound source or detector, said rigid, plastic holder is of a generally predetermined shape and three dimensional dimensions without an inserted ultrasound source or detector, said rigid, plastic holder comprises an interrogation region for interrogation of an exterior interrogation surface, said interrogation region is dimensioned to snugly fit over a housing or frame for said ultrasound source or detector while permitting interrogation through said interrogation region and said interrogation region engages with said ultrasound source or detector housing or frame,
 - e) an ultrasound probe mechanically compatible with said rigid, plastic holder, wherein the holder configured to be mechanically compatible with a plurality of differently sized ultrasonic probes, and
 - f) an ultrasound device for ultrasound interrogation, signal processing and conveyance of interrogation information.

71. A therapeutic kit, comprising:

- c) a rigid, plastic holder for an ultrasound source or detector, said rigid, plastic holder is of a generally predetermined shape and three dimensional dimensions without an inserted ultrasound source or detector, said rigid, plastic holder comprises an interrogation region for interrogation of an exterior interrogation surface, said interrogation region is dimensioned to snugly fit over a housing or frame for said ultrasound source or detector while permitting interrogation through said interrogation region and said interrogation region engages with said ultrasound source or detector housing or frame, and

B 5
d) a health care product in at least one dosage or a medical treatment; wherein said
interrogation device can assist in monitoring a therapeutic effect of said at least
one dosage

B 6
75. A device, comprising a rigid, plastic holder for an ultrasound source or detector, said
rigid, plastic holder is of a generally predetermined shape and three dimensional dimensions
without an inserted ultrasound source or detector, said rigid, plastic holder comprises an
interrogation region for interrogation of an exterior interrogation surface, said interrogation
region is dimensioned to snugly fit over a housing or frame for said ultrasound source or detector
while permitting interrogation through said interrogation region and said interrogation region
engages with said ultrasound source or detector housing or frame, wherein the holder configured
to be compatible with a plurality of differently sized ultrasonic probes.

82-79
83
80. The device of claim 1, wherein , the securing portion of the holder configured
to secure a plurality of differently sized ultrasonic probes.

80. The hygienic removable holder of claim 30 further including a collar which
secures the probe within the holder, said collar being configured to received more
that one size probe.